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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,812	08/17/2001	Lee-Hwei K. Sun	02SUN2001	5834
7590	03/09/2004			
EXAMINER				
DEBERRY, REGINA M				
ART UNIT			PAPER NUMBER	
1647				

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,812

Applicant(s)

SUN ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-15, 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/31/01</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of Application, Amendments and/or Claims

The amendment filed 17 August 2001 has been entered in full.

The information disclosure statement filed 31 October 2001 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Applicant's election of Group I, SEQ ID NO:18 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-3, 6-15, and 20 read upon elected SEQ ID NO: 18. Claims 4, 5, 16-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected SEQ ID NO; there being no allowable generic or linking claim. Election was made **without** traverse 21 August 2003.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-8, 10, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sudo *et al.*, (WO 99/58662, 11/18/99; in English EP 1 088 888 A1). The claims are drawn to a recombinant HuEPO-L-vFc fusion protein comprising HuEPO, a peptide linker, and a human IgG Fc variant and methods of making.

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Sudo *et al.* teach a fusion protein comprising a signal sequence, an immunoglobulin Fc region, a peptide linker and amino acid of a target protein (abstract, page 3, lines 1-20). Sudo *et al.* teach that the immunoglobulin Fc region is an amino acid sequence containing the carboxyl-terminal portion of an immunoglobulin H chain constant region. Sudo *et al.* teach that preferred Fc regions are those derived from immunoglobulin gamma, more preferably Fc regions derived from immunoglobulin gamma-1 containing part of the hinge region. Sudo *et al.* teach that substitutions, insertions and deletions can be made in the amino acid of the Fc regions (page 4, lines 9-39). Sudo *et al.* teach the target protein as erythropoietin (page 4, lines 48-49). Sudo *et al.* teach it is preferred to use a linker comprising about 5 to 50 amino acid residues. Sudo *et al.* teach methods of making the fusion protein purified from CHO cells (page 3, lines 22-29; page 6, lines 51-58 and page 7, lines 11-25). Sudo *et al.* teach the cell proliferation assays of the fusion protein (page 7, line 35-page 8, line 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sudo *et al.*, (WO 99/58662, 11/18/99) in view of Sytkowski *et al.* (Journal of Biological Chemistry 274:24773-24778, 1999). The teachings of Sudo *et al.*

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are described above. Sudo *et al.* does not teach peptide linkers comprising two or more amino acids selected from the group consisting of glycine, serine, alanine and threonine.

Sytkowski *et al.* teach fusion proteins consisting of two human erythropoietin domains linked by a 17 amino acid flexible peptide linker. Sytkowski *et al.* teach the sequence of the peptide linker as (GGGGS)₃ (Abstract and page 24774, Results, 1st paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Sudo *et al.* and Sytkowski *et al.* to make the instant invention of a recombinant HuEPO-L-vFc fusion protein comprising HuEPO, a peptide linker and a human IgG Fc variant. The motivation and expected success is provided by Sytkowski *et al.* who demonstrate that the length of the peptide linker functions to aid in stability and inhibit steric hindrance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are rejected because of the term "CHO-derived cell line". It is suggest that Applicants amend the claims to recite, "a CHO

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cell line transfected with DNA encoding the recombinant HuEPO-L-vFC fusion protein of claim..."

Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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3/2/04


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